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510(k) NOTIFICATION SUMMARY

I. General Information

APR 19 2007

A. Submission Applicant and Correspondent:

Name:	Abigo Medical AB
Address:	Ekonomivägen 5 S-436 33 Askim, Sweden Tel: 011-46-31-748-4950 Fax: 011-46-31-68-3951
US Agent and Correspondent:	Emalee G. Murphy Kirkpatrick & Lockhart Preston Gates Ellis LLP 1601 K Street, NW Washington, DC 20006 Tel: 202-778-9428 Fax: 202-778-9100 email: emalee.murphy@klgates.com

B. Name of Device

Trade Name:	Wound Dressing Sorbact® Wound Dressing
Common Name:	Nonabsorbable Gauze, Surgical Sponge & Wound and Burn Dressing for External Use

C. Regulatory Information:

Classification:	Unclassified
Product Codes:	FRO
Panel:	General and Plastic Surgery
Performance Standard:	No performance standard is applicable at this time.
Device Est. Reg.:	TBA

Sorbact® dressings are CE certified as Class IIb medical devices (for use principally with wounds that have breached the dermis and can only heal by secondary intent).

D. Devices to Which the New Device is Substantially Equivalent:

ColActiveAG Antimicrobial Gel Sheet Dressing (K052696)
Triosyn T40 Antimicrobial Wound Dressing (K051542)

II. Device Description:

Sorbact® Wound Dressings are sterile bandages that attract and capture water-repelling (hydrophobic) microorganisms. The dressings are coated with DACC (dialkyl carbamoyl chloride), a hydrophobic (water-repelling) fatty ester acid that binds to and reduces the

overall concentration of hydrophobic microbes in a wound each time the dressing is changed. Available Sorbact® products include adsorbent dressings, compresses, ribbon gauze tamponades, round swabs and surgical dressings.

III. Indications for Use

Rx: Sorbact® Wound Dressings are intended for use in the management of moderate to heavily exudating partial to full thickness wounds (including clean, colonized, contaminated or infected wounds) and to bind hydrophobic microbes [redacted] The dressing is indicated for post-operative wounds, trauma wounds, shallow cavity wounds, fistulas, pressure ulcers, diabetic ulcers, and venous ulcers.

OTC: Sorbact® Wound Dressings are intended for use in the management of draining minor wounds and to attract and bind water repelling germs. The dressing may be used on minor scrapes, cuts, sores and burns.

IV. Summary of Technical Characteristics of the Device Compared to the Predicate Devices

The Sorbact® wound dressings are substantially equivalent to FDA-cleared antimicrobial wound dressings ColActiveAG Antimicrobial Gel Sheet Dressing (K052696) and Triosyn T40 Antimicrobial Wound Dressing (K051542).

All three dressings consist of well-known bandage materials: Sorbact® uses sterile hydrophobic acetate or cotton fabric, plus the absorption dressing has an absorption core of non-woven viscose. Colactive AG uses a sterile hydrated collagen sheet; Triosyn T40 uses a layer of absorbent non-woven polyester with a non-adherent high-density polyethylene mesh (HDPE).

All three dressings are indicated for the management of full and partial thickness wounds including various types of ulcers (pressure, diabetic, venous ulcers), abrasions and lacerations, traumatic wounds, and surgical wounds.

All three dressings indicated for prescription use, are sterile, and claim an antimicrobial activity. Sorbact® acts by adsorption to remove bacteria from a wound, while Colactive AG and Triosyn T40 include an antimicrobial active substance as part of the device.

The difference in the mechanisms of antimicrobial action does not affect the substantial equivalence of Sorbact® dressings.

Substantial Equivalence Comparison Chart:

Product Name	Sorbact®	ColactiveAG	Triosyn T40
Manufacturer	Abigo Medical AB	Covalon Technolgies Ltd.	Triosyn Corp.
Regulatory Status	Wound Dressing 21 CFR 807.87 Product Code FRO	K032986	K051542
Materials of Construction	A layer of sterile hydrophobic acetate or cotton fabric, plus the absorbent dressing has an absorption core of non-woven viscose. The wound contact materials are coated with a fatty ester that gives Sorbact® a strong hydrophobic (water-repelling) property.	Collagen and silver lactate provided in a sterile hydrated collagen sheet.	A single layer of Triosyn composite sterile dressing consisting of an absorbent polyester non-woven pad, a permeable adhesive, iodinated resin beads, and a non-adherent high-density polyethylene mesh (HDPE).
Sterility	Yes	Yes	Yes
Comparable Sizes and Forms	Yes	Yes	Yes
Biocompatibility Testing	Yes	Yes	Yes
Intended Use	Rx: For the management of moderate to heavily exudating partial to full thickness (clean, colonized, contaminated or infected) wounds, including post-operative wounds, trauma wounds, shallow cavity wounds, fistulas, pressure ulcers, diabetic ulcers, and venous ulcers.	Rx: For the management of full and partial thickness wounds including pressure and diabetic ulcers, mixed vascular etiology ulcers, venous ulcers, donor and graft sites, abrasions and lacerations, traumatic wounds healing by secondary intention, dehisced surgical wounds, and first and second degree burns.	Rx: For use in partial and full thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, first-and-second degree burns, donor sites and surgical wounds. May be used over debrided and grafted partial thickness wounds.
	OTC: For the management of superficial wounds such as minor abrasions, cuts, pressure	No	No

	sores and burns.		
Antimicrobial Effect	Yes	Yes	Yes

V. Tests and Conclusions

Sorbact® wound dressings have been shown in studies, including *in vitro* and clinical tests, to be safe and effective for their intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2007

Abigo Medical SA
% Kirkpatrick & Lockhart Preston
Gates Ellis, LLP
Ms. Emalee G. Murphy
1601 K Street Northwest
Washington, District of Columbia 20006-1600

Re: K063059
Trade/Device Name: Sorbact® Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 22, 2007
Received: March 23, 2007

Dear Ms. Murphy:

This letter corrects our substantially equivalent letter of April 19, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBA

Device Name: Sorbact® Wound Dressing

Indications For Use:

Rx: Sorbact® Wound Dressings are intended for use in the management of moderate to heavily exudating partial to full thickness wounds (including clean, colonized, contaminated or infected wounds) and to bind hydrophobic microbes. The dressing is indicated for post-operative wounds, trauma wounds, shallow cavity wounds, fistulas, pressure ulcers, diabetic ulcers, and venous ulcers.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063059

Indications for Use

510(k) Number (if known): K063059

Device Name: Sorbact® Wound Dressings

Indications For Use:

Sorbact® Wound Dressings are intended for over-the-counter use in the management of draining minor wounds and to attract and bind water repelling germs. The dressings may be used on minor scrapes, cuts, sores and burns

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K063059

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)